SECTION E: 510(k) SUMMARY K013068

This summary of safety and effectiveness information is submitted in compliance with 21CFR807.92.

November 9, 2001

Submitter Information:
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268

Contact Person: Margo Enright
Phone Number: 317-870-5610
FAX Number: 317-870-5608

Trade Name:
BioScanner Glucose Test Strips

Classification Name: Glucose test system

Panel: Clinical Chemistry 75

Product Code: NBW

Device Classification: Class II

Intended Use
The BioScanner Glucose Test Strips are intended to be used by healthcare professionals to measure glucose in whole blood and by individuals with diabetes to measure fingerstick whole blood at home. Glucose measurements are used in the management of carbohydrate metabolism disorders.

Device Description
Glucose in the whole blood sample reacts with glucose oxidase in the presence of peroxidase, 4-aminoantipyrine and a di-substituted aniline to produce a colored end product. The BioScanner reads the percent reflectance of the color produced and converts reflectance into glucose concentration.

Predicate Device Information

STATEMENT OF SUBSTANTIAL EQUIVALENCE

Polymer Technology Systems, Inc. intends to introduce into commercial distribution the BioScanner Glucose Test Strips for the quantitative determination of Glucose in human whole blood. The BioScanner Glucose Test Strips are substantially equivalent to the predicate device noted below.

Name:	Accu-Chek Comfort Curve Test Strips
Device Company:	Roche Diagnostics
510(k) Number:	K 982002

Similarities and Differences (Predicate and BioScanner Glucose)

Similarities

- Both systems measure Glucose concentrations in blood.
- Both systems provide a result that correlates to the laboratory plasma glucose result.
- Both systems are calibrated with a glucose hexokinase laboratory method as the reference.
- Both reagents are similar in their composition in that both use a glucose oxidase reaction.
- Both systems require a lot specific memory chip for result calculation. Both systems contain the lot specific memory chip in the same package with the strips

Differences

- The Accu-Chek testing principle is based on an amperometric method in which a small current produced in a chemical reaction is measured and converted to a glucose result.
- The BioScanner Glucose Test Strips use reflectance photometry to measure a color change that is converted to a glucose result.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 4 - 2005

Ms. Margo Enright
Manager of Clinical Affairs
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268

Re: k013068
Trade/Device Name: BioScanner Glucose Test Strips
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II, Class II
Product Code: NBW, CGA
Dated: March 23,2005
Received: March 28,2005

Dear Ms. Enright:

This letter corrects our substantially equivalent letter of August 28, 2001 regarding the indications for is for your device. These types of devices are cleared for management of carbohydrate metabolism disorder and not for diagnosis of such disorders.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K013068

Device Name: BioScanner Glucose Test Strips

Indications For Use:
The BioScanner Glucose Test Strips are intended to be used by healthcare professionals to measure glucose in whole blood and by individuals with diabetes to measure glucose in fingerstick whole blood at home. Glucose measurements are used in the management of carbohydrate metabolism disorders.

Prescription Use X (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

ion Sign-Off

ffice of In Vitro Diagnostic Device
valuation and Safety

K013068